



IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

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B611.11

In re Application of:

Takao Takaya et al.

Serial No.: 07/229,489

Art Unit 122

Filed: August 8, 1988

For: NOVEL CRYSTALLINE 7-[2-(2-AMINOTHIAZOL-
4-YL)-2-HYDROXYIMINOACETAMIDO]-3-VINYL-
3-CEPHEM-4-CARBOXYLIC ACID (SYN ISOMER)

DECLARATION

I, TAKAO TAKAYA, a citizen of Japan residing at No. 1-5-87, Suimeidai, Kawanishi, Hyogo, Japan, declare and say that:

I graduated from University of Osaka Prefecture, Department of Chemistry, in March 1963;

I received the degree of Doctor of Technology, in 1968 from said University;

From 1968 to 1970, I had studied, as a postdoctoral fellow, chemistry and photochemistry of heterocyclic compounds under the guidance of Professor R. A. Abramovitch at University of Alabama, Alabama, U. S. A.;

From 1970 to 1971, I had studied, as a postdoctoral fellow, studies on heterocyclic compounds under the guidance of Professor A. I. Meyers at Wayne State University, Michigan, U. S. A.;

Since November 1971, I have been, as an organic chemist, in the continuous employ of Fujisawa Pharmaceutical Co., Ltd., Osaka, Japan and am now a director of the New Drug Research Laboratories;

I am a member of the Chemical Society of Japan;

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I am a co-inventor of the above-identified U.S. patent application;

I prepared the following test samples of the above-identified U.S. patent application and of U.S.P. 4,559,334 according to the methods disclosed therein.

Test Sample

Sample 1 --- the compound of Example 14 of U.S.P. 4,559,334

Sample 2 --- the compound of Example 16 of U.S.P. 4,559,334

Sample A --- Crystal A of the present application

The samples 1, 2 and A were delivered to Mr. Yoshihiko Okamoto for use in comparative tests on stability.

It is declared by the undersigned that all statements made herein of undersigned's own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.


Takao Takaya

This 20th day of October, 1989
Osaka, Japan



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4-YL)-2-HYDROXYIMINOACETAMIDO]-3-VINYL-
3-CEPHEM-4-CARBOXYLIC ACID (SYN ISOMER)

DECLARATION

I, Yoshihiko Okamoto, citizen of Japan residing at 1-8-6,
Takawashi, Habikino-shi, Osaka-prefecture, Japan declare and
say that:

I graduated from Osaka University, the Faculty of
Pharmaceutical Science, in March 1971;

I received the degree of Master of Pharmaceutical
Science, in 1973 from the same University;

Since April 1973, I have been, as an analytical
chemist, in the continuous employ of Fujisawa Pharmaceutical
Co., Ltd., Osaka, Japan and am now a senior scientist of the
analytical research Laboratories;

I am a member of the Pharmaceutical Society of Japan;

I have received from Dr. T. Takaya the test samples
(Sample 1, Sample 2 and Sample A) and conducted the
following comparative test on stability.

[I] Test Method

The stability of each test sample was examined under
the condition of 50°C in a closed container.

The potency of each sample was determined by liquid chromatography and the residual percentage to the initial value was calculated.

[II] Test Results

The potency (%) of each test sample after one month was shown in the following table (initial = 100%).

Test Sample	Potency (%)
Sample 1	68.4
Sample 2	26.4
Sample A	99.3

As apparent from the test results, Sample A is more stable than Sample 1 or Sample 2.

It is declared by the undersigned that all statements made herein of undersigned's own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Y. Okamoto
Yoshihiko Okamoto

This 23rd day of October, 1989
Osaka, Japan